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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/806,906	03/23/2004	Jonathan J. Langberg	MITRAL.001C3	2408

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EDWARDS LIFESCIENCES CORPORATION
LEGAL DEPARTMENT
ONE EDWARDS WAY
IRVINE, CA 92614

EXAMINER	
SCHILLINGER, ANN M	

ART UNIT	PAPER NUMBER
3774	

MAIL DATE	DELIVERY MODE
10/29/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/806,906	LANGBERG ET AL.	
	Examiner	Art Unit	
	Ann Schillinger	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 12, 13, 19-25, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. (US Pat. No. 6210432) in view of Oz et al. (US Pat. No. 6269819). For claim 1, Solem et al. discloses advancing, manipulating, and adjusting the prosthesis in col. 2, lines 9-35. In this disclosure, Solem shows it is capable of being adjusted any number of time, thus meeting the added limitations for first, second, and third configurations of the stent. Solem et al. does not disclose monitoring hemodynamic function before the adjustment. Oz et al. teaches this in col. 8, lines 1-18 and col. 9, lines 33-43 for the purpose of allowing the surgeon to control bleeding. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to monitor the hemodynamic function in order to allow the surgeon to control bleeding.

For claim 19, Solem et al. discloses advancing, manipulating, and adjusting the prosthesis in col. 2, lines 9-56. Solem et al. does not disclose monitoring the degree of regurgitation in the valve before the adjustment. As stated above, Solem shows it is capable of being adjusted any number of time, thus meeting the added limitations for first, second, and third configurations of the stent.Oz et al. teaches this in col. 8, lines 1-18 and col. 9, lines 33-43 for the purpose of allowing the surgeon to control bleeding. Therefore, it would have been obvious to one of

ordinary skill in the art at the time the invention was made, to monitor the degree of regurgitation in the valve in order to allow the surgeon to control bleeding.

Solem et al. discloses the limitations of claims 2 and 21 in col. 4, lines 6-7.

Oz et al. discloses the limitations of claims 3 and 22 in col. 2, lines 33-46.

Solem et al. discloses the limitations of claims 4 and 23 in Figure 12 and col. 4, lines 62-65.

Solem et al. discloses the limitations of claim 5 in col. 2, lines 46-47 and in col. 5, line 12.

Solem et al. discloses the limitations of claims 6 and 24 in col. 5, lines 1-4.

Solem et al. discloses the limitations of claims 7 and 25 in col. 4, lines 56 through col. 5, line 4.

Oz et al. discloses the limitations of claims 12 and 30 in col. 10, lines 31-67.

Oz et al. discloses the limitations of claims 13 and 31 in col. 9, lines 63-67.

Solem et al. discloses the limitations of claim 20 in col. 4, lines 56-67.

Claims 8-11 and 26-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of Wright (US Pat. No. 5522884). Solem et al. and Oz et al. disclose the invention substantially as claimed, but they do not disclose the specific locking means claimed by the Applicant. Wright teaches these means in col. 2, line 63 through col. 3, line 53 for the purpose of affixing the necessary parts of the prosthesis in their appropriate positions. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use the locking means in order to affix the necessary parts of the prosthesis in their appropriate positions.

Claims 14 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of Fowler, Jr. et al. (US Pat. No. 5086776). Solem et al. and Oz et al. disclose the invention substantially as claimed, but they do not disclose using surface echo cardiography. Fowler, Jr. et al. teaches using surface echo cardiography in col. 1, lines 20-21 to utilize its noninvasive properties. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use surface echo cardiography in order to utilize its noninvasive properties.

Claims 15 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of Killman (US Pat. No. 5846198). Solem et al. and Oz et al. disclose the invention substantially as claimed, but they do not disclose using intracardiac echo cardiography. Killman teaches using intracardiac echo cardiography in col. 2, line 55 through col. 3, line 2 for the purpose of improving imaging of the procedure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use intracardiac echo cardiography in order to improve imaging of the procedure.

Claims 16 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of Mehta (US Pat. No. 5476453). Solem et al. and Oz et al. disclose the invention substantially as claimed, but they do not disclose using fluoroscopy with radiocontrast media. Mehta teaches using fluoroscopy with radiocontrast media in col. 1, lines 34-67 for the purpose of visually guiding the procedure. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use fluoroscopy with radiocontrast media in order to visually guiding the procedure.

Claims 17 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of McIntyre (US Pat. No. 52918953). Solem et al. and Oz et al. disclose the invention substantially as claimed, but they do not disclose using wedge pressure measurements to monitor hemodynamic function. McIntyre teaches using wedge pressure measurements to monitor hemodynamic function in col. 15, line 61 through col. 16, line 15 for the purpose of utilizing its noninvasive properties. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use wedge pressure measurements to monitor hemodynamic function in order to utilize its noninvasive properties.

Claims 18, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solem et al. in view of Oz et al. in further view of Kadhiresan (US Pat. No. 5935081). Solem et al. and Oz et al. disclose the invention substantially as claimed, but they do not disclose using an ongoing drug therapy. Kadhiresan teaches using an ongoing drug therapy in col. 4, lines 8-46 for the purpose of improving the patients' quality of life. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to use an ongoing drug therapy in order to improve the patients' quality of life.

Response to Arguments

Applicant's arguments filed 8/7/2007 have been fully considered but they are not persuasive. Regarding the Solem et al. reference, column 2 states the Solem et al. stent is adjustable as it is capable of being bent and/or shortened. This indicates that the stent may be adjusted as many time as needed in order to properly fit into its desired location. With this adjustability, the stent is capable of meeting the new claim limitations of having three different configurations available to the user. Column 2 in Solem et al. discusses a first and a second state

of the prosthesis. These "states" refer to the intial and final positions of the stent, and does the temporary, adjustment states that meet the claim limitations into account.

Regarding the Oz et al. reference, the applicant contends that Oz et al. fails to teach or suggest adjusting a prosthesis to a third configuration different from the second configuration in response to a monitoring step. However, as stated above and in the previous office action, the Solem et al. reference discloses the step of adjusting the prosthesis. The Oz et al. reference was used to *only* teach step of monitoring of hemodynamic function, which is described in col. 8, lines 1-18 and col. 9, lines 33-43.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
October 25, 2007

CORRINE McDERMOTT
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700